REMARKS

Applicant respectfully requests entry of this paper into the application *only if the claimed invention will be deemed allowable*. In the eventuality that this case goes to appeal, the amendments presented herein are hereby vacated, and applicant will appeal the claims as previously presented.

This amendment follows an amendments filed under 37 CFR § 1.116 on May 10, 2005, which apparently have not been entered into the file. The changes shown above indicate changes to the claims compared with the claims as presented on September 23, 2004. Certain claims are cancelled, and other claims have been amended to indicate that the histone deacetylase inhibitor used is butyrate, which is illustrated at several places in the Detailed Description and in the Examples. Thus, no new matter is added, and the claims now cover butyrate and its equivalents. Claims 13-15, 19-24, 26-32, 34-38 are pending in the application, and under examination.

Reconsideration and allowance of the application is respectfully requested.

Double Patenting

The pending claims stand provisionally rejected for obviousness-type double patenting over certain claims of copending application USSN 10/087,142.

The prosecution of the present application is more advanced than the 10/087,142 application. Accordingly, it is expected that the present application will issue as a U.S. Patent first, and no terminal disclaimer is required.

The pending claims also stand rejected for obviousness-type double patenting over claims 1-3 of U.S. Patent 6,458,589. The Office Action indicates that the claims in the present application are obvious because the cell populations of the '589 patent have the same characteristics as cells produced by the methods of the instant claims.

Applicant disagrees. Even if the Office is entitled to use a one-way test in this instance, applicant respectfully submits that the test has been applied the wrong way around. The question is not whether the claims in the issued patent are obvious with respect to the claims here, but the opposite — whether the *method* claimed here is obvious with respect to the *product* claimed in the issued patent. The test is applied to the claims alone, without regard to what is taught in the specification. See MPEP § 804 (II)(B)(1)(a).

The methods claimed here explicitly require the use of *butyrate* as an *ingredient* in the method. The use of butyrate is not taught or suggested in the *claims* of the issued patent.

The most recent Advisory Action indicates that butyrate was inherently present in the hepatocyte lineage cells claimed in the issued patent. Applicant again disagrees. First of all, there is nothing that ties the claims of the patent to the conditions of one of the working examples as the only possible embodiment. The claims explicitly cover cells having the required characteristics; nothing else is required to be present. Furthermore, even if the user chooses to use butyrate as a hepatocyte differentiation agent to produce the claimed product of the '589 patent, they may readily obtain a population of pPS derived hepatocyte lineage cells free of butyrate simply by washing them.

Thus, butyrate is not in the claimed product of the '589 patent as an explicitly required feature, and the doctrine of obviousness-type double patenting does not apply. Withdrawal of this rejection is respectfully requested.

Rejection under 35 USC § 112

The pending claims also stand rejected under 35 USC § 112 ¶ 1 as not being enabled for making hepatocytes from pPS cells with histone deacetylase inhibitors other than 5 mM butyrate. The Office Action refers again to the article by Lee et al. (Genesis 38:32, 2004) as teaching that the effect of butyrate on embryonic stem cell differentiation is dose-dependent.

Applicant respectfully disagrees. It is unnecessary for the claims to indicate the concentration of butyrate needed to effect differentiation into hepatocyte lineage cells. The specification exemplifies butyrate concentrations that are effective. Should the reader decide to deviate from the exemplified concentration, this can be done without undue experimentation — the protocol is just repeated at an altered butyrate concentration, and the cell culture is monitored for the presence of hepatocyte lineage cells having the characteristics required by the claim. Thus, a full working range of effective concentrations can easily be determined without undue experimentation.

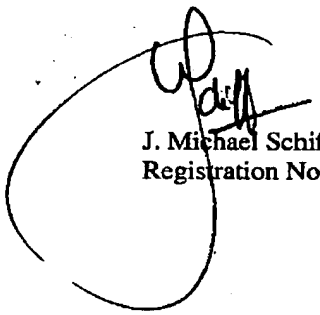
As explained previously, the skilled reader can use the same empirical approach to determine as a matter of routine experimentation what other histone deacetylase inhibitors are effective in making hepatocyte lineage cells from pPS cells, and what an optimum concentration would be. Nevertheless, to advance prosecution of the application, the claims have now been amended so as to explicitly recite butyrate as a preferred histone deacetylase inhibitor. Applicant reserves the right to present claims to methods using other hepatocyte differentiation agents in another application.

Withdrawal of this rejection is requested.

The application is believed to be in condition for allowance, which is hereby requested.

No fee is believed due for entry or consideration of this Amendment. Nevertheless, should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



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